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PTO/SB/21 (08-03)

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<b>TRANSMITTAL FORM</b>  (to be used for all correspondence after initial filing)	Application Number	10799,941	
	Filing Date	03/11/2004	
	First Named Inventor	Martha G. Welch	
	Art Unit	1615	
	Examiner Name	to be assigned	
Total Number of Pages in This Submission	25	Attorney Docket Number	5199-134

ENCLOSURES (Check all that apply)		
<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____	<input type="checkbox"/> After Allowance communication to Technology Center (TC) <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): 86 references
<b>Remarks</b> Form PTO/SB/08B and duplicate (22 pages) Information Disclosure Statement (2 pages) 86 references Return Postcard		
SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT		
Firm or Individual name	Todd Holmbo, Reg. No. 42,665	
Signature		
Date	07/06/2005	

CERTIFICATE OF TRANSMISSION/MAILING		
I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.		
Typed or printed name	Debbie Jenkins	
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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: Martha G. Welch *et al*                      Docket No.: 5199-134  
Serial No.: 10/799,941                      Examiner: to be assigned  
Filed: March 11, 2004                      Group Art Unit: 1615  
Title: NOVEL MULTYPEPTIDE REGIMENT FOR THE TREATMENT OF AUTISTIC  
SPECTRUM, BEHAVIORAL, EMOTIONAL AND VISCERAL INFLAMMATION/  
AUTOIMMUNE DISORDERS

July 6, 2005

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 C.F.R. §1.97(c)**

Sir:

In accordance with the duty of disclosure under 37 C.F.R. §1.56, applicant hereby notifies the U.S. Patent and Trademark Office of the following documents, which are listed on the attached PTO/SB/08B form. The examiner may deem these documents to be relevant to patentability of the claims of the above-identified application. The submission of the listed documents is not intended as an admission that any of the documents constitute prior art against the claims of the present application. Applicants do not waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.


Applicants respectfully request that the listed documents be considered by the examiner and be made of record in the present application and that initialed a copy of form PTO/SB/08B be returned in accordance with MPEP §609.

It is understood that no fee is necessary for submission of this Information Disclosure Statement, because it is being filed before the later of three months from the filing date or the mailing of the first Office Action on the merits.

The Commissioner is hereby authorized to charge payment of any fees associated with this application or credit any overpayment to Deposit Account No. 02-4270.



Respectfully submitted,

  
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Substitute for form 1449/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

**Complete if Known**

Application Number	10/799,941
Filing Date	03/11/2004
First Named Inventor	Martha G. Welch
Art Unit	1615
Examiner Name	
Attorney Docket Number	5199-134

Sheet

1

of

11

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	1	Abad C, Martinez C, Juarranz MG, Arranz A, Leceta J, Delgado M, Gomariz RP. Therapeutic effects of vasoactive intestinal peptide in the trinitrobenzene sulfonic acid mice model of Crohn's disease. Gastroenterology. 2003 Apr;124(4)	
	2	Anisman H, Merali Z. Cytokines, stress and depressive illness: brain-immune interactions. Ann Med. 2003;35(1):2-11	
	3	Armando I, Carranza A, Nishimura Y, Hoe KL, Barontini M, Terron JA, Falcon-Neri A, Ito T, Juorio AV, Saavedra JM. (2001) Peripheral administration of an angiotensin II AT(1) receptor antagonist decreases the hypothalamic-pituitary-adrenal response to isolation stress. Endocrinology. Sep;142(9):3880-9	
	4	Asarian L, Yousefzadeh E, Silverman AJ, Silver R. Stimuli from conspecifics influence brain mast cell population in male rats. Horm Behav. 2002 Aug;42(1):1-12. (not available - License restricted)	
	5	Aylward EH, Minshew NJ, Goldstein G, Honeycutt NA, Augustine AM, Yates KO, Barta PE, Pearlson GD. MRI volumes of amygdala and hippocampus in non-mentally retarded autistic adolescents and adults. Neurology. 1999 Dec 10; 53(9): 2145-50	
	6	Baker H, Joh TH, Ruggiero DA, Reis DJ. Variations in number of dopamine neurons and tyrosine hydroxylase activity in hypothalamus of two mouse strains. J Neurosci. 1983 Apr;3(4):832-43	
	7	Baron-Cohen S, Ring HA, Wheelwright S, Bullmore ET, Brammer MJ, Simmons A, Williams SC. Social intelligence in the normal and autistic brain: an fMRI study. Eur J Neurosci. 1999 Jun; 11(6):1891-8	
	8	Bauman M, Kemper TL. Histoanatomic observations of the brain in early infantile autism. Neurology. 1985 Jun; 35(6): 866-74	
	9	Bauminger N, Kasari C. Loneliness and friendship in high-functioning children with autism. Child Dev. 2000 Mar-Apr; 71(2): 447-56. (not available)	
	10	Bayliss WM and Starling EH (1902) The mechanism of pancreatic secretion. J Physiol (Lond) 28, 325-353	

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SignatureDate  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

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	11	Bitton A, Sewitch MJ, Peppercorn MA, deB Edwardes MD, Shah S, Ransil B, Locke SE. Psychosocial determinants of relapse in ulcerative colitis: a longitudinal study. Am J Gastroenterol. 2003 Oct;98(10):2203-8	
	12	Blair HT, Schafe GE, Bauer EP, Rodrigues SM, LeDoux JE. Synaptic plasticity in the lateral amygdala: a cellular hypothesis of fear conditioning. Learn Mem. 2001 Sep-Oct;8(5):2	
	13	Bregonzio C, Armando I, Ando H, Jezova M, Baiardi G, Saavedra JM. (2003) Anti-inflammatory effects of angiotensin II AT1 receptor antagonism prevent stress-induced gastric injury. Am J Physiol Gastrointest Liver Physiol. .2003 Aug;285(2):G414-23	
	14	Breiner J, Beck S. (1984) Parents as change agents in the management of their developmentally delayed children's noncompliant behaviors: a critical review. Appl Res Ment Retard.;5(2):259-78. - (not available)	
	15	Buchsbaum MS, Hollander E, Haznedar MM, Tang C, Spiegel-Cohen J, Wei TC, Solimando A, Buchsbaum BR, Robins D, Bienstock C, Cartwright C, Mosovich S. Effect of fluoxetine on regional cerebral metabolism in autistic spectrum disorders: a pilot study. Int J Neuropsychopharmacol. 2001 Jun; 4(2): 119-25. - (not available)	
	16	Chariton CG, Miller RL, Crawley JN, Handelsmann GE, O'Donohue TL. Secretin modulation of behavioral and physiological functions in the rat. Peptides. 1983 Sep-Oct;4(5):739-42	
	17	Charlton CG, O'Donohue TL, Miller RL, Jacobowitz DM. Secretin immunoreactivity in rat and pig brain. Peptides. 1981;2 Suppl 1:45-9	
	18	Chugani DC, Muzik O, Rothermel R, Behen M, Chakraborty P, Mangner T, da Silva EA, Chugani HT. Altered serotonin synthesis in the dentatohalamocortical pathway in autistic boys. Ann Neurol. 1997 Oct;42(4):666-9	
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	20	Comi AM, Zimmerman AW, Frye VH, Law PA, Peeden JN. Familial clustering of autoimmune disorders and evaluation of medical risk factors in autism. J Child Neurol. 1999 Jun; 14(6): 388-94	

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		Application Number	10/799,941
		Filing Date	03/11/2004
		First Named Inventor	Martha G. Welch
		Art Unit	1615
Examiner Name			
Sheet 3	of 11	Attorney Docket Number	5199-134

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	21	Cook EH. Autism: review of neurochemical investigation. Synapse. 1990; 6(3): 292-308	
	22	Cushing BS, Yamamoto Y, Hoffman GE, Carter CS. Central expression of c-Fos in neonatal male and female prairie voles in response to treatment with oxytocin. Brain Res Dev Brain Res. 2003 Jul 12; 143(2): 129-36	
	23	Dantzer R. Cytokine-induced sickness behavior: mechanisms and implications. Ann N Y Acad Sci. 2001 Mar;933:222-34	
	24	Delgado M, Leceta J, Sun W, Gomariz RP, Ganea D. VIP and PACAP induce shift to a Th2 response by upregulating B7.2 expression. Ann N Y Acad Sci. 2000; 921: 68-78	
	25	Dohi T, Fujihashi K, Rennert PD, Iwatani K, Kiyono H, McGhee JR. Hapten-induced colitis is associated with colonic patch hypertrophy and T helper cell 2-type responses. J Exp Med. 1999 Apr 19; 189(8): 11 169-80	
	26	Drossman DA, Ringel Y, Vogt BA, Leserman J, Lin W, Smith JK, Whitehead W. Alterations of brain activity associated with resolution of emotional distress and pain in a case of severe irritable bowel syndrome. Gastroenterology. 2003 Mar;124(3):754-61	
	27	Eskandari F, Webster JI, Stenberg EM. Neural immune pathways and their connection to inflammatory diseases Arthritis Res Ther. 2003;5(6):251-65. – (not available – License restriction)	
	28	Farmer MA, Sundberg JP, Bristol IJ, Churchill GA, Li R, Elson CO, Leiter EH. A major quantitative trait locus on chromosome 3 controls colitis severity in IL-10-deficient mice. Proc Natl Acad Sci U S A. 2001 Nov 20; 98(24): 13820-5. Epub 2001 Nov 13	
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	30	Francis DD, Diorio J, Plotsky PM, Meaney MJ. Environmental enrichment reverses the effects of maternal separation on stress reactivity. J Neurosci. 2002 Sep 15;22(18):7840-3	

Examiner Signature	Date Considered
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	31	Francis DD, Young LJ, Meaney MJ, Insel TR. Naturally occurring differences in maternal care are associated with the expression of oxytocin and vasopressin (Vla) receptors: gender differences. J Neuroendocrinol. 2002 May; 14(5): 34	
	32	Friebe-Hoffmann U, Chiao JP, Rauk PN. Effect of IL-1beta and IL-6 on oxytocin secretion in human uterine smooth muscle cells. Am J Reprod Immunol. 2001 Sep; 46(3): 226-3 1. – (not available)	
	33	Gandhi S, Tsueshita T, Onyuksel H, Chandiwalla R, Rubinstein 1. (2002) Interactions of human secretin with sterically stabilized phospholipid micelles amplify peptide-induced vasodilation in vivo. Peptides. ug;23(8):1433-9	
	34	Gassull MA. Nutrition and inflammatory bowel disease: its relation to pathophysiology, outcome and therapy. Dig Dis. 2003; 21(3): 220-7.	
	35	Gershon MD and D'Autreaux F. Personal communication 2003 – (not available)	
	36	Gershon MD. (1998) The Second Brain: a groundbreaking new understanding of nervous disorders of the stomach and intestine. New York: Harper Collins.p.163. – (not available)	
	37	Guilloteau P, Chayvialle JA, Toullec R, Grongnet JF, Bernard C. Early-life patterns of plasma gut regulatory peptide levels in calves: effects of the first meals. Biol Neonate. 1992;61(2):103-9.	
	38	Gupta S, Aggarwal S, Rashanravan B, Lee T. Th1- and Th2-like cytokines in CD4+ and CD8+ T cells in autism. JNeuroimmunol. 1998 May 1; 85(1): 106-9.	
	39	Guth PH, Smith E. The effect of gastrointestinal hormones on the gastric microcirculation. Gastroenterology. 1976 Sep;71(3):435-8	
	40	Gutkowska J, Jankowski M, Mukaddam-Daher S, McCann SM. Oxytocin is a cardiovascular hormone. Braz J Med Biol Res. 2000 Jun;33(6):625-33	

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	41	Hart A, Kamm MA. Review article: mechanisms of initiation and perpetuation of gut inflammation by stress. Aliment Pharmacol Ther. 2002 Dec; 16(12):2017-28	
	42	Haznedar MM, Buchsbaum MS, Wei TC, Hof PR, Cartwright C, Bienstock CA, Hollander E. (2000) Limbic circuitry in patients with autism spectrum disorders studied with positron emission tomography and magnetic resonance imaging. Am J Psychiatry. Dec; 157	
	43	Helou CM, Imbert-Teboul M, Doucet A, Rajerison R, Chollet C, Alhenc-Gelas F, Marchetti J. (2003) Angiotensin receptor subtypes in thin and muscular juxtamedullary efferent arterioles of rat kidney. Am J Physiol Renal Physiol. Sep;285(3):F507-14	
	44	Higa KT, Mori E, Viana FF, Morris M, Michelini LC. Baroreflex control of heart rate by oxytocin in the solitary-vagal complex. Am J Physiol Regul Integr Comp Physiol. 2002 Feb;282(2):R537-45	
	45	Hollander E, Novotny S, Hanratty M, Yaffe R, DeCaria CM, Aronowitz BR, Mosovich S. (2003) Oxytocin infusion reduces repetitive behaviors in adults with autistic and Asperger's disorders. Neuropsychopharmacology. Jan;28(1):193-8	
	46	Horvath K, Papadimitriou JC, Rabsztyrn A, Drachenberg C, Tildon JT. (1999) Gastrointestinal abnormalities in children with autistic disorder. J Pediatr. Nov; 135(5):559-63	
	47	Horvath K, Penman JA. (2002) Autism and gastrointestinal symptoms. Curr Gastroenterol Rep. Jun;4(3):251-8. – (not available)	
	48	Horvath K, Stefanatos G, Sokolski KN, Wachtel R, Nabors L, Tildon JT. (1998) Improved social and language skills after secretin administration in patients with autistic spectrum disorders. J Assoc Acad Minor Phys.; 9(1): 9-15	
	49	Iijima H, Takahashi I, Kishi D, Kim JK, Kawano S, Hori M, Kiyono H. (1999) Alteration of interleukin 4 production results in the inhibition of T helper type 2 cell-dominated inflammatory bowel disease in T cell receptor alpha chain-deficient mice. J Exp Med. Sep 6; 190(5): 607-15.	
	50	Jyonouchi H, Sun S, Itokazu N. Innate immunity associated with inflammatory responses and cytokine production against common dietary proteins in patients with autism spectrum disorder. Neuropsychobiology. 2002;46(2):76-84	

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		First Named Inventor	Martha G. Welch
		Art Unit	1615
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